Canada. National Health and Welfare, Department of.
Food and Drug Directorate

FOOD & DRUG

RESEARCH AND ADMINISTRATION

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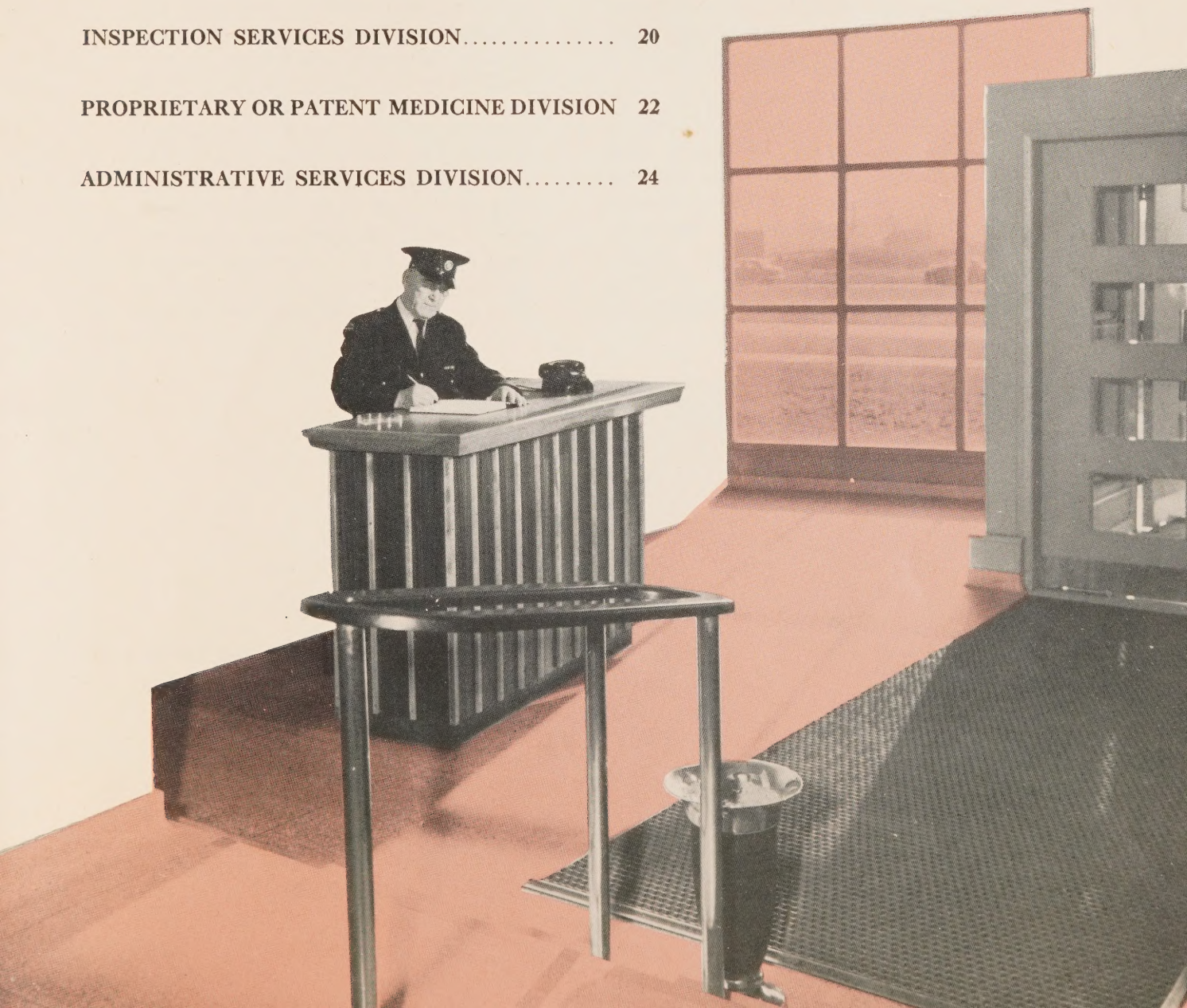


FOOD AND DRUG RESEARCH AND ADMINISTRATION
DEPARTMENT OF NATIONAL HEALTH AND WELFARE
OTTAWA

FOOD & DRUG DIRECTORATE

In May 1874 the parliament of Canada passed an act to prevent the sale of adulterated food, drink and drugs. This act, from which the Food and Drugs Act of 1953 stems, was enforced from January 1st, 1875. There has been food and drug control in Canada on a national scale since that time.

The Food and Drug Directorate is an organization in the Department of National Health and Welfare for the administration and enforcement of the Food and Drugs Act and the Proprietary or Patent Medicine Act. It consists of a Laboratory Services Division, an Inspection Services Division, an Administrative Services Division, and a Proprietary or Patent Medicine Division, all in Ottawa, and five regional Divisions, each having laboratory, inspection and administrative services. Every Region has a headquarters and district offices. There is a main laboratory at each regional headquarters and some district laboratories. Several inspectors are located at each regional headquarters and there are one or more inspectors in each district.

The administration and enforcement of the two Acts depends in a large measure on scientific information and methods. The laboratories of the directorate are, therefore, a very important part of the organization. Research and investigative work form a substantial part of the job of the central laboratories at Ottawa and to a lesser degree are carried out in the regional laboratories too. Mainly, the analytical work required in the enforcement program is done in the regions.

The laboratory work involves the use of many techniques and covers several fields of science. Recent advances have provided instruments and methods which make it possible to determine rapidly and accurately the presence of inorganic and organic compounds in foods and other products. The laboratories use and need all types of these instruments so that the

View of the Board Room

best and most rapid methods will be employed in protecting the Canadian consumer.

The Inspection Services apply the information and advice supplied by the Laboratory Services in their efforts to obtain compliance with the law. The work of the inspectors is complicated and difficult and an acquaintance with several branches of applied science is necessary. They must also be able to obtain the confidence and cooperation of the industry and trade.

The Proprietary or Patent Medicine Division is concerned mainly with the registration of medicines under the Proprietary or Patent Medicine Act and the review of labels and advertising claims for these medicines. In enforcement in the field, assistance is provided by the field inspectors. The policies of this division in administration and enforcement are closely integrated with those employed for the Food and Drugs Act.

Attached to the Director's office there is a Medical Section and a Consumer Relations Section.

The Administrative Services provide clerical and stenographic services, collect and tabulate information, prepare requisitions for equipment and supplies, record expenditures, distribute information to the trade, supervise stores and supply office management for the Directorate.

In the course of its duties the Directorate consults several advisory boards and panels before establishing policy or amending the regulations. These boards and panels are composed of scientists and medical men from universities and industry. Professional and trade associations are also consulted for advice and information needed for proper administration of the law and development of regulations. These trade associations are concerned with or are producing different types of food, drug and cosmetic products.

In January 1956 the headquarters staff of the Food and Drug Directorate occupied a new building designed and constructed especially for their work. This building provides the necessary modern accommodation for an organization which has a great responsibility in assuring the consumer that his food and drink are wholesome and safe, that his drugs are safe when taken under the conditions recommended, that cosmetics are not harmful and that all are honestly advertised and packaged.

Staff Training and Lecture Room

CONSUMER RELATIONS SECTION

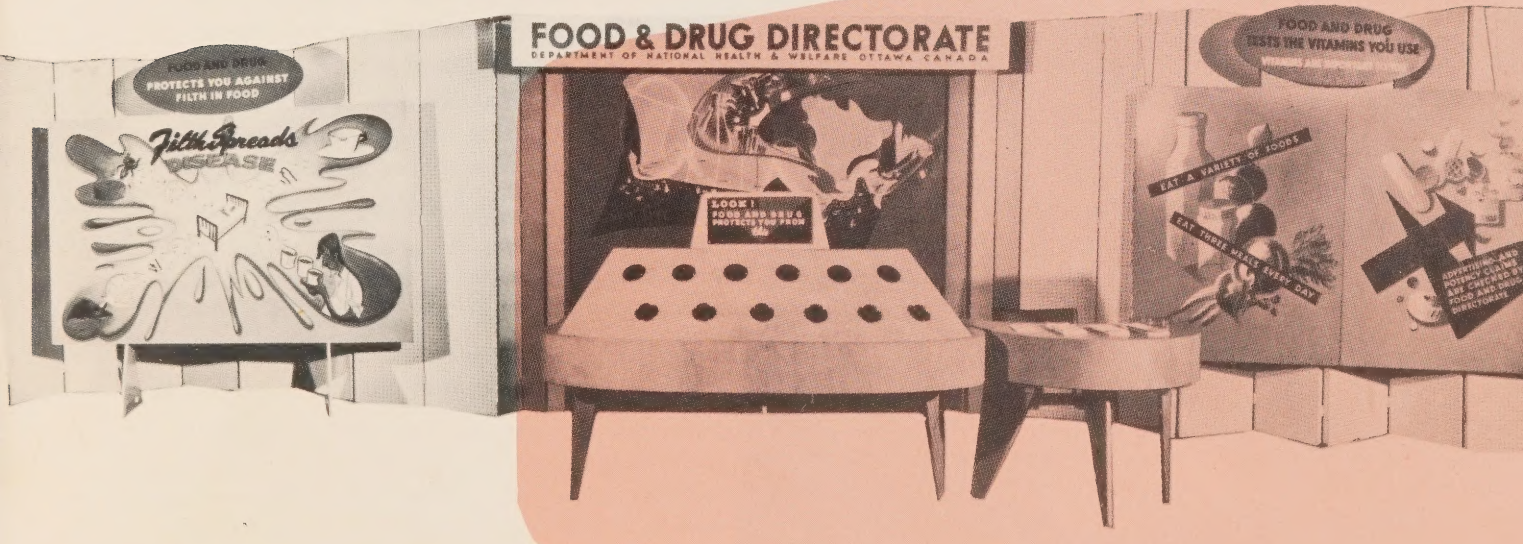
The purpose of the Food and Drugs Act is primarily consumer protection; protection against health hazards and fraud in the advertising, sale and use of foods, drugs, cosmetics and medical devices. It is most important that consumers and the general public be aware of the existence of this organization so that they may know where to bring their complaints and their problems.

The function of this section is to provide information to the general public for these expressed objectives and to co-ordinate similar work of all divisions of the Directorate.

Pamphlets describing the work and bringing any particular appropriate matter to the attention of the public are prepared and distributed. These booklets are distributed to societies and organized groups as well as to individual consumers.

Displays depicting the organization, fields of interest and methods of working of the Directorate are shown at many exhibitions, conventions and universities across Canada. These exhibits also provide an opportunity for distribution of pamphlets, discussion of standards and other requirements of the Acts as they affect the consumer. Press releases on matters of general interest are issued and assistance is provided to writers preparing magazine articles and radio or television scripts dealing with food and drug subjects.

A collection and recording of all speeches and other informational material from the regions and other divisions is made and contact with consumer organizations is maintained and coordinated.



A Typical Food and Drug Display

MEDICAL SECTION

The Medical Section of the Food and Drug Directorate is concerned primarily with the medical aspects of the problems involved in the Food and Drugs Act. In this respect it is charged with examining and evaluating the clinical aspects of the claims made for foods and drugs by the manufacturers. It is also concerned with reviewing the medical claims made for foods and drugs in all advertising media including broadcast and telecast.

The medical section looks after the processing of new drug submissions. It is responsible for the final evaluation of the clinical toxicity of the new products before these products can be sold to the general public. It acts in an advisory capacity to the Proprietary or Patent Medicine Act, offering advise on the acceptability of products and on the advertising of such items.

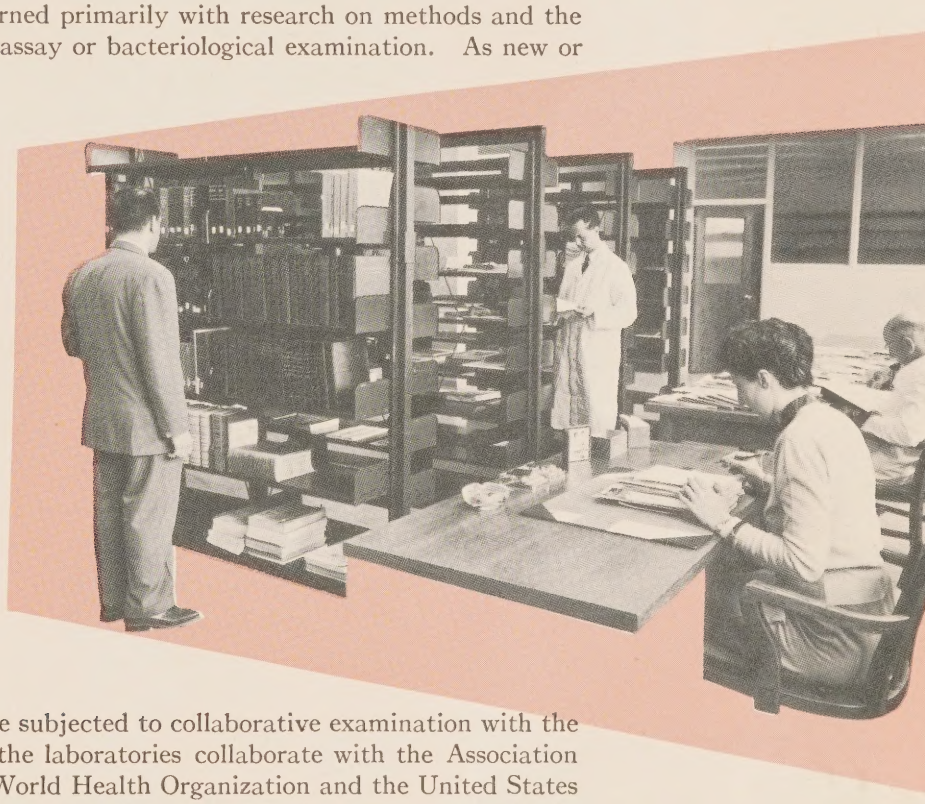
The medical section acts as a liaison between the Food and Drug Directorate and such other organizations as the Medical Division of the United States' Food and Drug Administration, the American Medical Association and The Canadian Medical Association. With the Canadian Pediatric Society it is playing a very active role in the establishment of Poison Control Centres throughout Canada. In this it has undertaken the task of assembling and disseminating information on the potentially toxic ingredients of certain household remedies and chemicals. The medical section will act as the clearing house for the collection of statistics accumulated at each of the Poison Centres.

Director's Staff

LABORATORY SERVICES

The Laboratory Services of the Food and Drug Directorate include the headquarters Laboratory at Ottawa and the Regional Laboratories situated at Halifax, Montreal, Toronto, Winnipeg and Vancouver. There are also small district laboratories attached to some inspection offices. The Ottawa Laboratory is divided into the following sections: Pharmacology and Toxicology, Vitamins and Nutrition, Physiology and Hormones, Microbiology, Animal Pathology, Cosmetics and Alcoholic Beverages, Organic Chemistry, Pharmaceutical Chemistry, Biometrics, Biophysics, Food Chemistry and Workshop.

The Ottawa Laboratory is concerned primarily with research on methods and the analyses of drugs requiring biological assay or bacteriological examination. As new or revised methods are developed they are subjected to collaborative examination with the Regional Laboratories. In addition, the laboratories collaborate with the Association of Official Agricultural Chemists, the World Health Organization and the United States Pharmacopoeia in developing or devising methods and establishing reference standards.



Library and Reading Room

The Ottawa Laboratory also conducts some basic research in pharmacology, physiology, chemistry and microbiology.

Regional Laboratories assist in the development of methods by taking part in collaborative trials and do much the greater part of the analytical work on foods and drugs necessary in obtaining compliance with the law. A large variety and considerable volume of work is carried out by these laboratories.

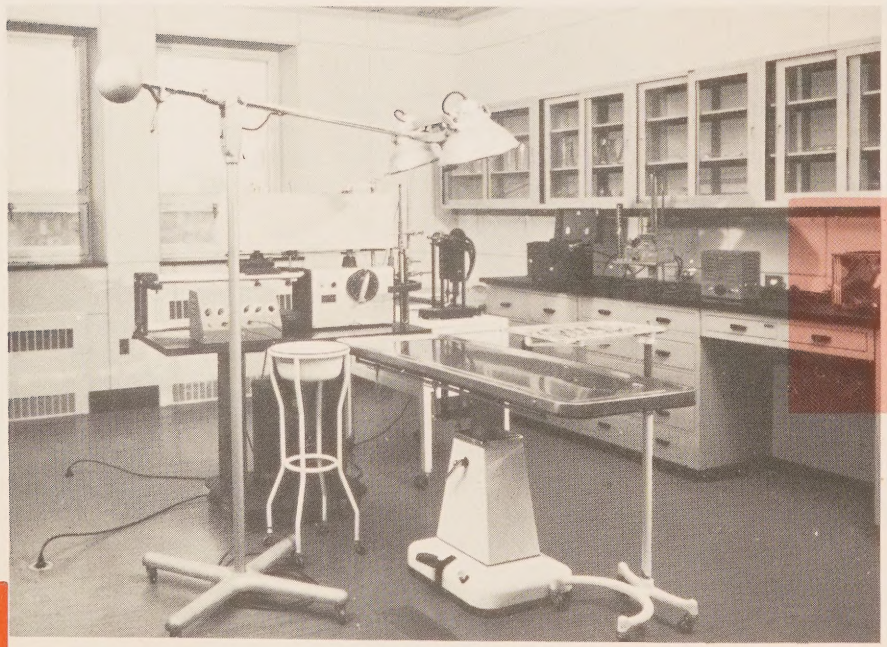
In addition to laboratory work the heads of sections in the Ottawa Laboratory and the superintendents of the Regional Laboratories supply information and advice of a technical nature required in administering the two Acts for which the Directorate is responsible. They also assist in drafting amendments to regulations.

A well-appointed library provides essential source material as well as study facilities. An effective inter-library loan system permits comprehensive searches of the scientific literature to be carried out.

PHARMACOLOGY AND TOXICOLOGY SECTION

The work of this Section is chiefly concerned with investigational and research work in pharmacology, including studies in acute and chronic toxicity, therapeutic action, site and mode of action, storage, excretion and metabolism, and in the biochemical, physiological, and anatomical effects of drugs or chemical agents. Some of this work is in connection with substances suspected of being adulterants or toxicants in foods, drugs and cosmetics. Another important aspect of the work is to originate and improve methods for testing drugs for potency; and to prepare and approve a number of standards used as reference standards to check market products. The appraisal of new drugs, chemical food additives, and pesticides for safety of use comes within the scope of the work of the Section.

Personnel of the Section act as consultants to other Divisions within the Department on pharmacological and toxicological matters.



Pharmacology and Toxicology Section: Equipment for Mammalian Pharmacological Studies: Chymograph, Operating-Table, Respiration Pump, Visocardiette, Electromanometer, etc.

VITAMIN AND NUTRITION SECTION

Vitamins are added to foods such as enriched bread, margarine and evaporated milk and are contained in many drugs. It is the responsibility of this laboratory (1) to ensure that these preparations contain the vitamins in the amounts listed on the label, (2) to develop methods of assay for vitamins, and (3) to study problems related to the nutritional properties of food and drugs. Chemical methods are used whenever possible but it is sometimes necessary to use the growth of microorganisms, or, as in the case of vitamin D, to use especially prepared rats.

Nutritional studies with rats are designed to determine the effect of various types of food enrichment and of modern trends in food processing on the nutritive properties of food.

Studies on human subjects are conducted to determine the availability of vitamins and other nutrients in food dietary supplements and pharmaceutical preparations. Other studies are in progress on nutritional qualities of oils and amino acids and the effect of various fatty acids in the diet.

Vitamins and Nutrition Section: Weighing Rats in Amino-Acid Experiments.

PHYSIOLOGY AND HORMONES SECTION

The Physiology and Hormones Section is mainly responsible for drugs which either contain hormones or possess a hormone-like activity. Periodically surveys are conducted of hormone preparations which are available to the Canadian public in order to check both the potency and the identity of the biologically active ingredients. Products which contain a purified crystalline substance such as the anti-arthritic hormone cortisone, or one of the sex homones, are analysed by recognized physical or chemical methods and insulin and corticotrophin (ACTH) are assayed biologically. A Canadian Reference Standard is employed to estimate the biological potency of the material under test.

The section is also concerned with such problems as the safety of meat from cattle or poultry to which hormones have been administered. The meat from such animals must not contain any detectable hormone residue. A method has been developed that will detect as little as five parts of stilbestrol per billion parts of meat.

Physiology and Hormones Section: Biological Assay of Insulin. The Sloping Screen is employed to detect the hypoglycemic response of the mice treated with insulin.

MICROBIOLOGY SECTION

The work of the Microbiology Section at present has to do with all aspects of the behaviour of the bacteria or other microscopic creatures ("microorganisms") that are important if they get into or upon food. These are of three main types:

(1) The microorganisms that grow in food and bring about "digestive" processes quite similar to what goes on in our own stomachs so that the food is "spoiled" and becomes unsightly or evil-smelling or of unpleasant taste.

(2) The microorganisms that can cause infections in man and which can be carried around passively in or upon foods. The most common ones would be the bacteria that cause intestinal upsets.

(3) Those bacteria that multiply in foods and as they grow release into the food poisonous substances, or "toxins", which when eaten by man can cause various illnesses ranging from simple vomiting and diarrhoea to a fatal paralysis.

In addition, other forms of "extraneous matter" are watched for, either because their presence in foods could be esthetically offensive or could mean that the food had been exposed to unsanitary conditions that might have allowed dangerous bacteria to get into the foods. Clearly, for foods to be safe and wholesome none of these effects are tolerable. Hence, an important assignment is the development of methods necessary to see that objectionable bacteria and extraneous matter have been kept out of foods.

This also involves appropriate tests to verify whether manufacturing and processing of foods has been carried out in clean sanitary establishments.

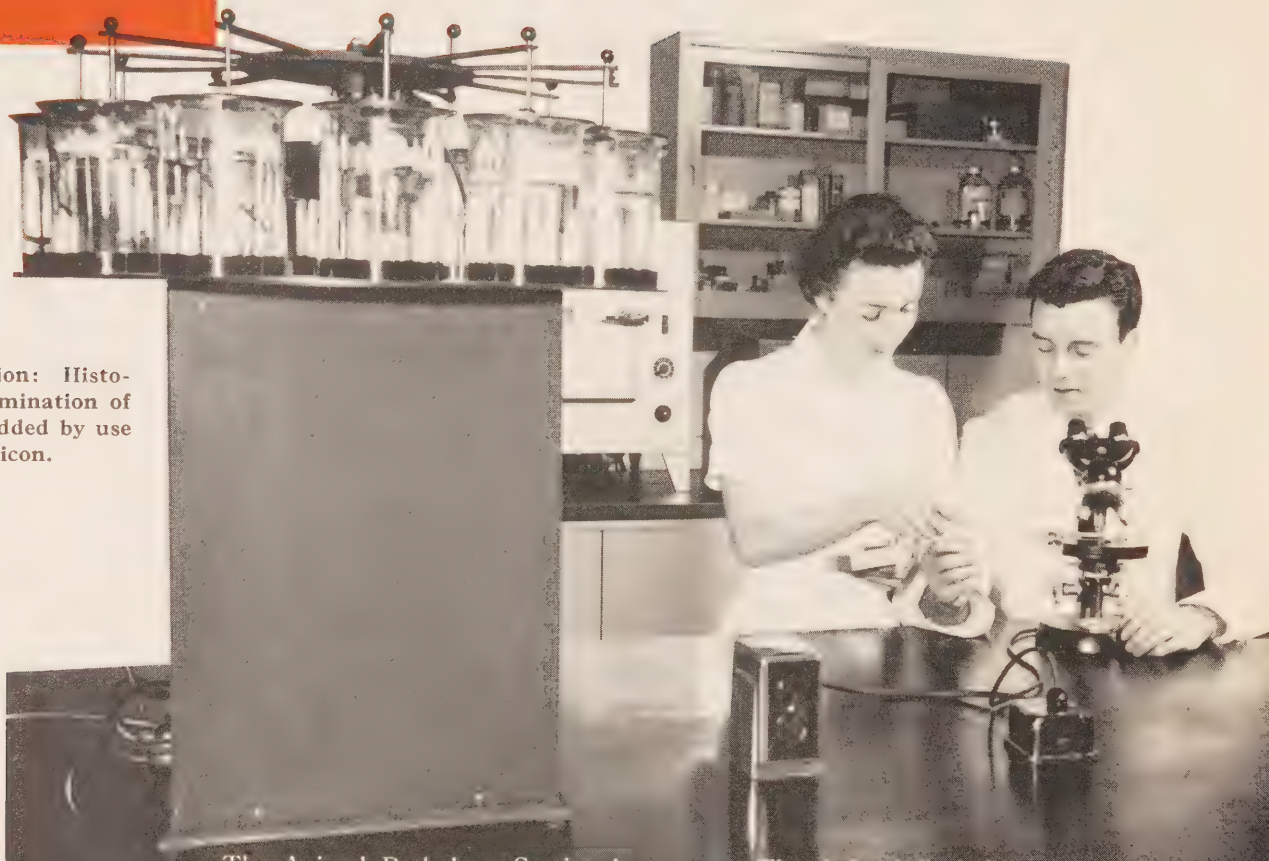
The section also carries on experiments to learn more about the different "toxins". For instance, how they can be detected and identified; what kind of substance they are and what conditions favour their formation and how best to prevent this.

The number of particular kinds of bacteria that can be tolerated and are unlikely to cause harm when found in foods is estimated in order that "standards" may be proclaimed, so that foods may not be sold if they contain more than these safe numbers.

The staff must also undertake the necessary study and experiments to be able to advise the executive of the Directorate on the probable significance of new technical developments on the microbiological picture in foods and to determine to what extent could health hazards or spoilage problems develop as a result.

Microbiology Section: General bacteriology and separation of toxins by paper electrophoresis.

ANIMAL PATHOLOGY SECTION



Pathology Section: Histo-pathological examination of specimens embedded by use of the autotechnicon.

The Animal Pathology Section is concerned with the changes that may take place in the tissues and organs of animals used for experimental purposes. When animals have been given drugs or food substances that are being tested, the animals are submitted to the Pathology Section where a gross and microscopic examination is made of their tissues and organs. If changes are noted in the tissues or organs that are considered to be due to toxic effects of the substance fed to the animals this information along with information from the tests made by the chemists determines whether or not the food or drug is safe for human consumption.

The Animal Pathology Section is also concerned with the health and well-being of all animals in the Animal Colony. Animals in the colony are under veterinary supervision. They are vaccinated against all the infectious and contagious diseases that might occur in the colony. They are also treated for all ecto- and endo-parasites such as fleas and worms and sick animals are placed in an isolation room where they receive medical treatment and where they are out of contact with healthy animals.

The Animal Pathology Section is concerned then with the health of the living animal and with the tissues and organs of the experimental animal.

COSMETICS AND ALCOHOLIC BEVERAGES SECTION

This Section is concerned with cosmetics, food and other colouring matters and alcoholic beverages. Its function is to deal with the technical aspects of these subjects, with special reference to compliance with the Act and regulations, and to keep abreast of all developments in these fields.

In cosmetics, the purity, suitability and safety of ingredients, the investigation of complaints from users, and the development of methods of analysis form the main work of the Section.

The colour work of the Section involves the chemical analysis and certification of all food colours entering the country, except such as may be already certified by another government. The Section has developed methods of identification and separation of colours used in other countries, but not permitted in food here. A file of absorption spectra of these and other colours is maintained for reference. In alcoholic beverages the work is in the main confined to the examination of samples showing abnormalties and to the endeavour to maintain a small research program mainly concerned with the determination of trace materials.

Cosmetics and Alcoholic Beverages Section: The identification and estimation of food colours using the Carey automatic recording spectrophotometer.

The Organic Chemistry Section is well equipped for pure and applied research in the physical organic field. Investigations are underway on narcotic and barbiturate drugs, and essential oils. Some of the investigations include the physical and chemical characterization of organic substances, for purposes of identification and quantitative determination. The problem concerns the analysis of a general unknown and samples are submitted with no indication of composition. It is necessary to have available methods of analysis which will specifically identify the substance.

As an example, it is necessary for international control of narcotic drugs to have available methods of determining the origin of opium. Not only is it necessary to determine the identity of opium, as such, but it is also necessary to say what is the geographical origin of a given opium sample. For this purpose samples of opium, through the cooperation of the Narcotic Control Division have been obtained from many parts of the world. These samples are authenticated by the various governments and supplied to UNITED NATIONS for

ORGANIC CHEMISTRY SECTION

Organic Chemistr Section: Determi nation of Opiun Origin by mean of alkaloidal an electrophoreti procedures.

distribution. Based on the composition of these samples, unknowns can be discriminated with respect to origin to a very high degree of accuracy. Arrangements have been made for scientists to come to Canada to study these methods.

Another problem which has been intensively investigated in collaboration with other government laboratories is the identification of essential oils. Physical-chemical characterization has been carried out on several of the components of these oils. By means of the data it will be possible to detect and identify isolates in food, drug and cosmetic products.

The processes of isolation and characterization involve the study of counter-current and column partition equilibria, electro-phoresis, and paper chromatography as well as the usual organic chemical processes. Modern instrumentation techniques such as infrared, ultraviolet and X-ray diffraction spectrophotometry are used in connection with these studies.

The purpose of this laboratory is, primarily, to conduct research into the analysis of pharmaceutical preparations. It is necessary to cover a very wide range of products which includes such medicinals as those intended to treat ordinary coughs and colds as well as preparations employed in the treatment of hay fever, headaches, rheumatism, muscular aches and pains, high and low blood pressure and a host of other common disorders.

Many drugs come under the surveillance of this section. The narcotics which are used for severe pain; the barbiturates, those blessed sleep-givers; and numerous drugs such as the sulfonamides which are used in combatting bacterial infections. Only a small percentage of the vast number of drugs store items tested have been mentioned but it may serve to indicate the enormous variety of pharmaceuticals, which must be checked.

Pharmaceutical Chemistry: Spectrophotometry and titration.

PHARMACEUTICAL CHEMISTRY SECTION

The research projects under investigation are intended to develop new methods of assay for pharmaceuticals or to improve those already in existence and thus facilitate the enforcement of the Food and Drugs Act. One way of doing this is to provide faster and more accurate methods of analysis for pharmaceutical products. To meet this end, workers are continually trying to develop analytical techniques which facilitate the checking of drug products.

In addition, surveys are always in progress to determine whether the products on the market comply with the claims made on their labels and to ensure that the Canadian public have, at their disposal, ever better quality drugs.

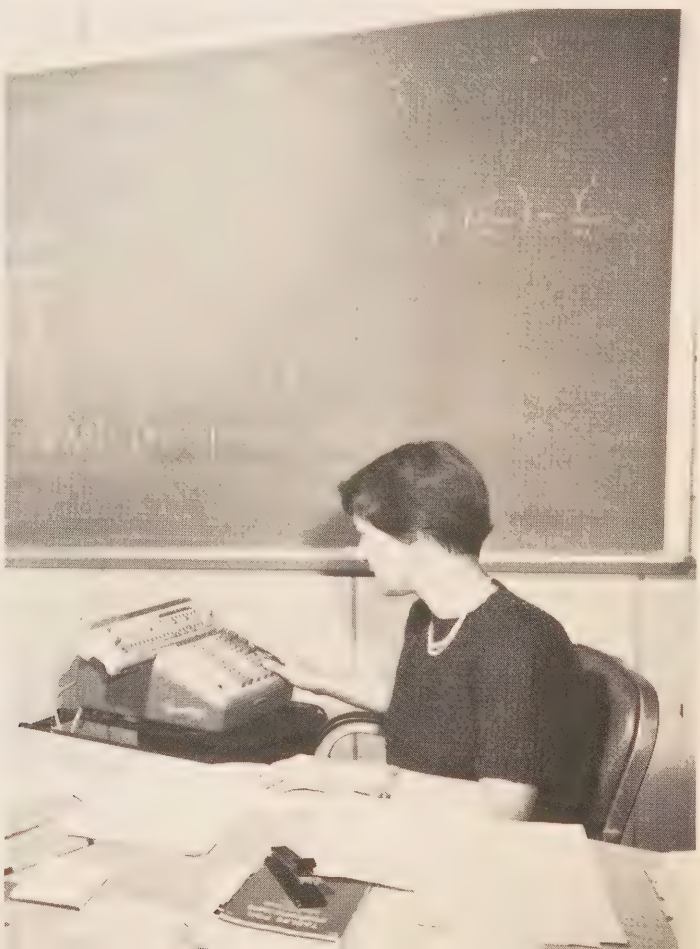
BIOMETRICS SECTION

The Biometrics Section engages, among other things, in the design and analysis of biological tests of all kinds and in working out designs for sampling many kinds of materials.

The scientific progress of the last twenty-five to thirty years has made this the Age of the Specialist. No scientist can work entirely alone today. There is always some portion of the problem he is studying that requires the attention of a specialist from some other area of science. So it is that the scientists and inspectors of the Food and Drug Directorate need the assistance of a scientist called a biometrician who specializes in a section of applied mathematics called statistics, or, when dealing with biological problems, biometry.

The biometrician is used as a consultant when aspects of research or examination requiring mathematical treatment appear. The scientist and inspector are perennially faced with the difficulty of too little time, too little space, too little material, and often, too little money to spend on the experiment or collection of samples for examination. Hence, it is essential that as much information as possible be derived from the work in the time and space available, within a rigid budget.

The biometrician is asked to consider the information required and the restrictions within which it may be obtained. From these specifications he draws up a plan or design to guide the scientist in his experiment and the inspector in collecting his samples. This plan is required to be the most efficient time-wise, cost-wise, equipment and supplies-wise and not least, information-wise.



Biometrics Section:
From mathematics to practical experimentation.

BIOPHYSICS SECTION

This is a newly established section whose primary concern is research on methods of appraisal of medical apparatus used by the medical profession or any other apparatus coming under this special class of instruments which are sold directly to the general public. When there is doubt as to the veracity of a sales promoting claim concerning a given instrument, tests are made on it to determine whether or not the instrument meets the advertised specifications. If it does not, appropriate action is taken to prevent deception of the public.

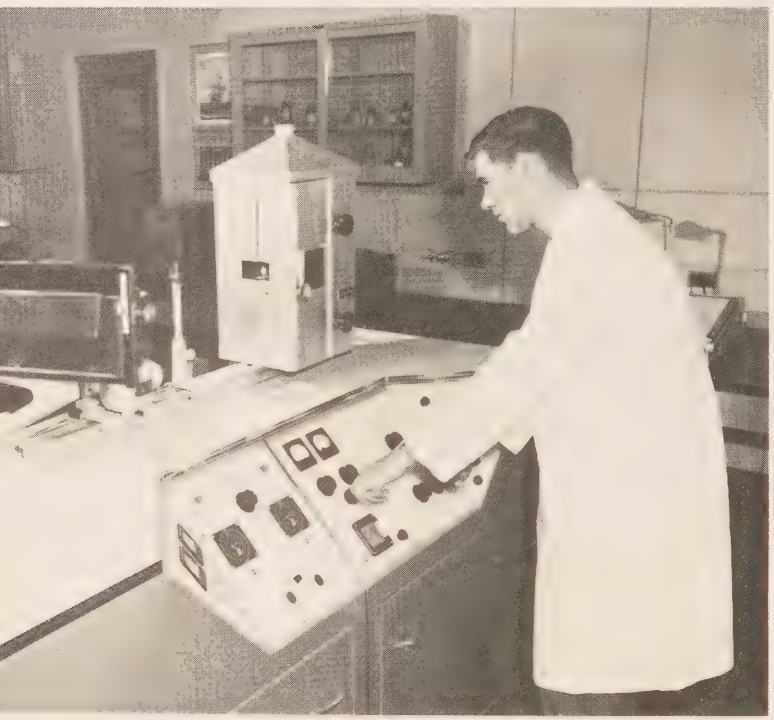
This section has also a research program involving the use of x-ray diffraction for the study and identification of new drugs and electron paramagnetic resonance to study radiation damage in food and drug material.

The Biophysics section also acts in an advisory capacity to other sections on matters involving physics.

Biophysics Section: Studying Radiation Damage in Food (Setting controls of the X-ray machine).

FOOD CHEMISTRY SECTION

The Food Chemistry Section is responsible for research on the development of analytical methods for the entire range of food products, with the exception of food colours and vitamins which are covered by other sections. Since well defined analytical methods are available for primary food constituents such as fat, protein, carbohydrate and so on, the efforts of this section are mainly devoted to research leading to the development of new methods for detecting food adulteration and for determining minor food constituents. It is this latter field to which our maximum research efforts are now devoted. During recent years, changes in the food processing industry have been particularly rapid. The use of new food additives to improve the texture, flavour and keeping qualities of food products has created new analytical problems that must be solved.



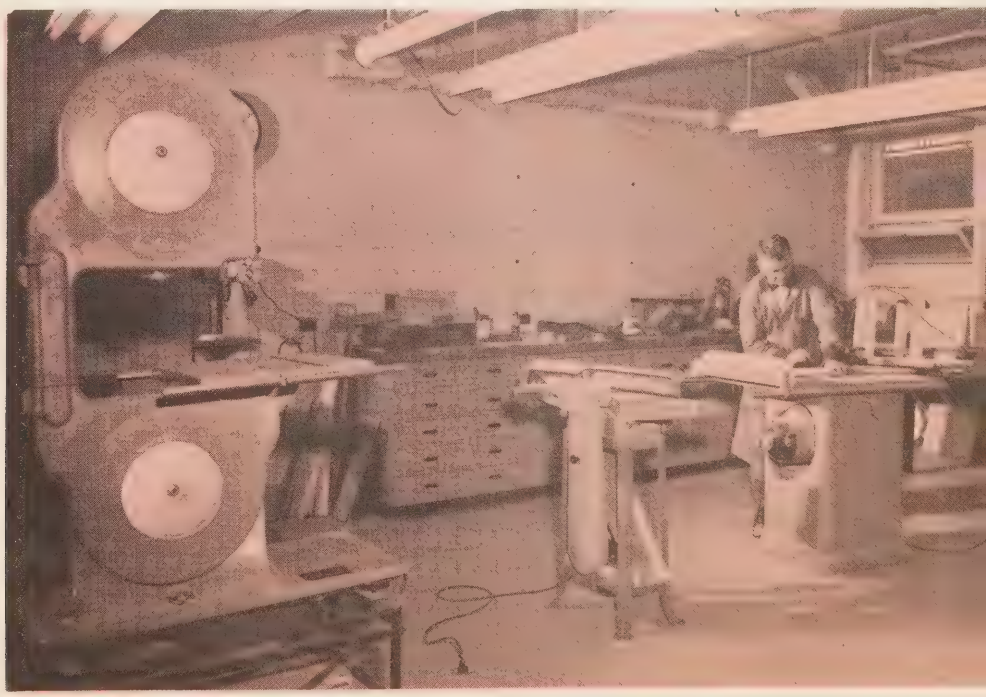
Food Chemistry Section: The determination of poisonous metals in foods with an emission spectrograph.

Today, a larger proportion of the nation's food supply is treated with chemical insecticides during its growth or storage, in order to prevent the staggering losses caused by insect damage. The types of chemicals permitted to be used and the conditions for their use on crops is such that no harmful residues should reach the consumer. Nevertheless, it is the duty of the Food Chemistry Section to conduct research to ensure that adequate methods are available so that the amount of such residues in foods, if any, can be accurately determined. This is a large and ever increasing assignment. The level of such pesticide residues is very small, being of the order, for example, of one part insecticide in one million parts of food. This corresponds to one ounce in sixty-two tons. Once satisfactory methods are available, the Regional Laboratories of the Food and Drug Directorate assume the equally enormous task of monitoring the nation's food supply in order to detect and stop adulteration as well as to ensure that harmful levels of insecticides or other food additives do not reach the consumer.

WORKSHOP

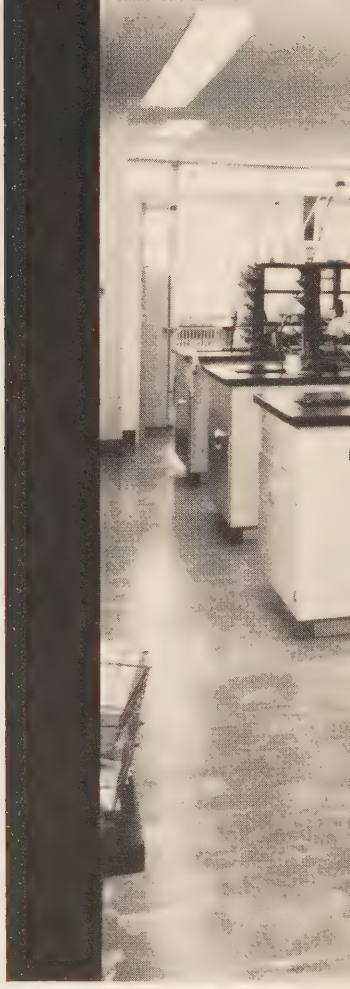
The Workshop located in the basement of the headquarters building provides an essential service to the research laboratories through the construction, repair and upkeep of laboratory equipment.

One section of the workshop is devoted primarily to woodworking while the other is used for metal working. A crib enclosed by means of wire mesh screen and fitted with metal shelving separates the two sections. The crib serves as a store room for the supplies for the workshop as well as a place to keep tools and instruments. Drills, presses, band saws, sanders and other machines are available and used in the construction of laboratory equipment not readily available from supply firms and in the repair and calibration of instruments used in the research laboratories.



The Workshop: Where intricate laboratory equipment is made and repaired.

REGIONAL AND DISTRICT OFFICES



During World War I it was realized that the wide expanse of the country made it very difficult to give proper service to the public and to industry from one central laboratory and administration at Ottawa. Those in parts of Canada many miles away found it difficult to get necessary information when they wanted it.

This situation led to the opening of what are now called Regional Offices and Laboratories in the larger cities across the country and each of these is responsible for giving service to the area surrounding it.

There is a regional office and laboratory at Vancouver which deals with Food and Drug matters in British Columbia, Alberta and the Yukon. Another is at Winnipeg which is responsible for the provinces of Saskatchewan, Manitoba and North Western Ontario. Farther east, a similar organization at Toronto looks after the more populated part of Ontario, and one in Montreal, the large, mostly French-speaking population of Quebec Province. The Maritime provinces and Newfoundland are dealt with through an office and laboratory in Halifax.

All these Regional Offices and Laboratories are coordinated with the large central office and laboratories in Ottawa, and the whole is under the control of the Food and Drug Director.

Each Regional office is operated by a Regional Director with the assistance of an Inspection Superintendent and a staff of Inspectors, a Laboratory Superintendent with a staff of chemists and technicians installed in a large well equipped laboratory, and a number of office personnel.

For the purpose of making still closer contact with the public and the trade some

A Typical Regional Laboratory

of the inspectors are further dispersed into the area by having a number of district offices set up in the smaller surrounding towns in each Region. A few of these district offices in the larger centres where there is a port, have a small laboratory.

As a result of this dispersal or decentralization, complaints from the public can be dealt with more promptly and by personal contact, better supervision of imports is affected, dangerous products can be removed more speedily from the market and, where necessary, quicker action can be taken against unscrupulous dealers. The Directorate can, in other words, do a better job of ensuring pure food and safe drugs for every Canadian.

In addition to the examination of single samples of domestic and imported foods, drugs and cosmetics, these laboratories carry out group surveys of products for conformity to the Food and Drugs Act and Regulations. Recent surveys of this type have included barbiturates, sulpha drugs, ferrous iron compounds, aminophylline and other drug preparations; preservatives in meats, insect and other infestation in canned corn, phosphatase in cheese, filth in cheese, composition of soluble coffees, content and fill of various types of containers. For some years there has been a National Survey of pharmaceutical vitamin preparations.

INSPECTION SERVICES DIVISION

Inspection Services charged with the enforcement actions in administration of the Food and Drugs Act and Regulations and with assistance in enforcing the Proprietary or Patent Medicine Act could be termed the eyes and ears of the Food and Drug Directorate. Members of the inspection team are situated in five regional and twenty-one district offices suitably located in the ten provinces These inspectors are in contact with the public, retailers, wholesalers and manufacturers, both of food and drugs and not only must find, but at times must sense, when things are wrong and set the machinery in motion to correct the infractions.

To carry out this enforcement most economically, inspection at the source is practiced. To this end inspectors have the authority to detain importations at Customs until evidence of compliance with our regulations is established. To aid in the examination of imported goods and to ensure expeditious release of shipments allowed entry, many of the district offices are equipped with small laboratories where the inspectors carry out examination of the goods.

Radio and television commercials referring to food, drugs, cosmetics and devices are reviewed for the Canadian Broadcasting Corporation. Labels and advertising are discussed with the Head Office of the firm responsible, by the appropriate Regional office except for national advertising which is dealt with at Ottawa.

Plant visits are made to check on processing and labelling and to ensure that foods and drugs are being processed and stored under adequate control and sanitary conditions. Since it has been estimated that there are more than 10,000 manufacturing establishments and some 70,000 retail outlets in Canada, a system of priorities has been set up to allow the conditions that might constitute serious health hazards to be given first attention. In this work close cooperation is maintained with other agencies, federal, provincial and municipal, since our work in this field is complementary to theirs.

Other fields of interest are the enforcement of prescription drug legislation, cooperation with other government agencies carrying out similar or allied work, and maintaining close contact with the consuming public and the trade through their various associations.

To implement our enforcement program, action may be taken in several different ways depending upon circumstances. Every effort is made to obtain the cooperation of the manufacturers in correcting infractions and in the majority of

Headquarters Inspection Services Staff

cases this has been successful. However, in some cases it becomes necessary to issue warnings, and sometimes to seize goods or to institute prosecution proceedings, or both.

To carry out these varied and comprehensive duties, an inspector is required to have a personality which lends itself to being able to work with the public or the manufacturer in an amiable manner and at the same time to be able to be insistent, when conditions warrant it, that corrective measures be taken. He must be able to converse intelligently on subjects ranging from simple labelling of food through discussion of therapeutic claims for drugs to an appreciation of what constitutes proper and adequate sanitary requirements and to serve as a prosecuting attorney or star witness in a court case. He needs a veritable store-house of technical information and to be a combination of diplomat and police officer. Inspectors are required to be graduates of a recognized university and the present staff includes men with degrees in chemistry, bacteriology, pharmacy and food technology.

PROPRIETARY OR PATENT MEDICINE DIVISION

The Proprietary or Patent Medicine Act, which came into force in 1909, is concerned exclusively with secret formula medicines sold under proprietary or trade names and its control rests mainly on registration before marketing and renewal of registration by annual licence.

Within the Department of National Health and Welfare, the Act is under the direct administration of the Chief of the Proprietary or Patent Medicine Division, who is responsible to the Director of the Food and Drug Directorate. Thus, the identification of the intent and effect of the Proprietary or Patent Medicine Act with the Food and Drugs Act is maintained but with such administrative recognition as to preserve the essential difference between the two statutes.

Registration is in the nature of the exercise of a discretion and two advisory bodies assist in the exercise of that responsibility. The Advisory Board established under the Act, has the responsibility of regulating the alcohol content of medicines and of defining the doses of the drugs listed in the schedule to the Act. Another board of medical officers, pharmacologists and other competent persons in the Department, assists in the assessment of therapeutic claims made for proprietarypreparations and determines if their medicinal ingredients are sufficient and suitable to support or to justify such claims.

A complete register of preparations is kept and continuously brought up-to-date so as to indicate which registrations are currently active and which ones have been discontinued. In 1956 this register showed 3,224 active registrations of medicines manufactured by 1,231 manufacturers located in various parts of Canada but mostly in Quebec and Ontario.

All registered preparations must be licensed every year and before the licence is granted, each preparation is examined to see if it conforms to the latest rulings and regulations and to the current general policies.

Another major function of this Division is to control commercial advertising of proprietary or patent medicines. Advertisements found in newspapers are examined every day by specially trained personnel of the Division. This includes newspapers from the most important cities across Canada. Objectionable publicity is promptly brought to the attention of the responsible manufacturer for correction.

Radio and television commercials for proprietary or patent medicines received from the Canadian Broadcasting Corporation are examined as to therapeutic claims and when necessary, criticized from the standpoint of the Act before final clearance by the Canadian Broadcasting Corporation.

This Division has the responsibility of ascertaining that registered preparations are properly compounded, correctly labelled and otherwise meet all the requirements of the Act.

Manufacturers of proprietary or patent medicines are required to submit their labels, circulars and other promotional literature at regular intervals. Actual working formulae are also requested periodically and are checked against the registered formulae.

In this connection much valuable information and assistance is supplied by the food and drug inspectors, who conduct manufacturing plant inspections, review advertisements in local publications and report irregularities involving proprietary or patent medicines, that may occur in their respective districts. Whenever necessary chemists of the Food and Drug Laboratories carry out analyses of samples.

Proprietary or Patent Medicine Division Staff

ADMINISTRATIVE SERVICES DIVISION

In order that the operative Divisions—Laboratory, Inspection and the Regions—may effectively perform their respective functions, various ancillary services must be maintained, such as clerical, stenographic and typing services and stores. These services are maintained by the Administrative Services Division. The sole purpose of this Division is to provide service, of many varied natures, to the personnel of the Laboratory and Inspection Divisions, both at headquarters and in the field.

It is in the Administrative Services Division that a complete record of all food and drug analyses made by the entire Directorate is maintained. From this record, which by the very nature of the works of the Directorate is highly complex, various statistical statements, with their attendant effect on current and future programming, are regularly compiled. Further, records are maintained showing the location of all Canadian and many foreign, food and drug manufacturing plants. All reports of sanitary inspections made by the Directorate are filed for reference and study. Trade Information Letters dealing with all subjects pertinent to the food and drug fields are dispatched from mailing lists which must be currently reviewed, in order that they may be kept up-to-date. Accounts payable by the Directorate are pre-audited and processed for payment. It is also a function of the clerical section of the Administrative Services Division to assist in the preparation of amendments to the Food and Drugs Act and Regulations and to process them for consideration of the Governor in Council.

Information Centre

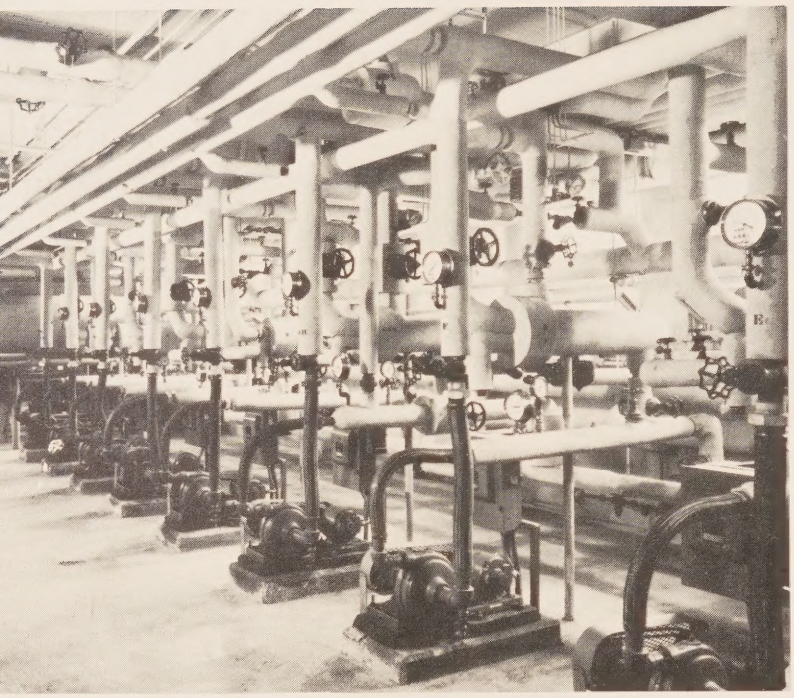
Stenographic Pool

Stores

Because so much of the Directorate's work is of a scientific nature, a staff of well-trained stenographers and typists provides dictation and transcription services to the operating division. Members of the Stenographic and Typing Section are trained to act, when called upon to do so, as secretaries to committees and meetings.

The Administrative Services Division also processes requisitions for the purchase of the great variety of materials and equipment required by the Directorate. The Stores Section is responsible for stocking, securing, and issuing nearly 4,000 different items ranging from common salt to rare and expensive chemicals, to delicate instruments and laboratory apparatus of many complex types.

In summary, the Administrative Services Division exists for the sole purpose of providing any service which will assist the technical divisions to perform their functions in an efficient and economical manner.



The Engineering Heart of the Food and Drug Building

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FOOD & DRUG RESEARCH & ADMINISTRATION

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